PRIVACY, CONDUCT, AND CONFLICT OF INTEREST

FOIA and Privacy

· Is my application confidential?

Most grant and contract materials are confidential, including grant applications, progress reports, contract proposals, and proceedings of review meetings. Two exceptions are the grant application's title and abstract, which NIH makes public.

Reviewers may not take materials from peer review and use them without attribution.

Can my grant be released to a third party through a Freedom of Information Act request?

Yes. Yes. NIH can release funded applications and research data in response to a FOIA request. NIH will notify the grantee before releasing information. The investigator will have the opportunity to identify any patentable information and information that is of commercial or financial nature. If the investigator wishes for certain portions of their grant application to be withheld prior to release, they will need to demonstrate that release of that information will reveal a trade secret or will result in substantial competitive harm. Personal information is also removed from the application prior to release under FOIA.

See Notice of Amendment of A-110 for guidance on access to research data.

What information does an applicant have the right to obtain about the review?

You have access to the summary statement available through <u>eRA Commons</u>. The summary statement consists of minimally edited critiques from each reviewer and a summary of the discussion at the review meeting. If the application is triaged, there is no discussion or summary.

Grantee and Contractor Conduct

What constitutes research misconduct?

The Office of Research Integrity (ORI, DHHS) handles allegations of research misconduct that involve PHS-supported research. Misconduct in research means fabrication, falsification, plagiarism, or any significant departure from accepted practices of the research community for proposing, performing, reviewing research or reporting research results. It does not include honest error or differences of opinion about interpretation of data. (a)Fabrication is making up data or results and recording or reporting them; (b)Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record; (c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

• If I encounter research misconduct, should I notify my program director?

No. The established procedure is to check with your institution for policies and procedure concerning allegations of possible research misconduct and they will direct you to the institutional

Research Integrity Officer (RIO). They will contact the NCI RIO, who will then initiate contact as required with the NIH Agency Extramural Research Integrity Officer (AERIO) and the DHHS Office of Research Integrity, ORI, Division of Investigative Oversight (DIO). The ORI website is http://ori.dhhs.gov.

Do NIH grantees and contractors have ethical requirements?

Yes. Grantees are subject to the regulations in the <u>NIH Grants Policy Statement on Ethical and Safe Conduct in Science and Organizational Operations</u>. Contractors must meet <u>Contractor</u> Qualifications.

Investigators involved in <u>human subjects</u> research must obtain education in protecting research participants. NCI offers an online <u>Human Participant Protections Education for Research Teams</u> course to meet the requirement.

. What are the conflict of interest requirements for grantees?

Each institution receiving PHS funds must have written policy guidelines on conflict of interest and avoidance thereof. These guidelines should reflect state and local laws and must cover financial interests, gifts, gratuities and favors, nepotism, and other areas such as political participation and bribery. These rules must also indicate how outside activities, relationships, and financial interests are reviewed by the responsible and objective institution official(s). See Conflict of Interest web site for more information.

The NIH has developed a web-based <u>Tutorial on Financial Conflict of Interest</u> which reviews the requirements of, and the Institutional and Investigator responsibilities for compliance with, the regulation. The tutorial is designed for use by Institutional officials responsible for managing NIH funded projects and for individuals who are responsible for the design, conduct or reporting of NIH-supported research.

· Do financial conflicts of interest need to be reported?

Yes. Grantees and contractors must report any financial conflict of interest (FCOI) before spending funds under a new award. If a conflict arises during an award, report it immediately. For grants, all FCOI reports should be sent to the appropriate Chief Grants Management Officer (http://grants.nih.gov/grants/stafflist_gmos.htm) of the NIH funding Institute/Center. For contracts, reports should be sent to the appropriate Director, Office of Acquisitions. (http://oamp.od.nih.gov/AcquisitionOffices/chief_cos1.asp).

Effective October, 2008, all Federal Demonstration Partnership (<u>FDP</u>) members may submit information using the <u>Financial Conflict of Interest (FCOI) Module</u>, a new feature of the NIH electronic Research Administration (eRA) Commons. The FCOI Module provides institutional users the ability to electronically prepare and submit FCOI reports and other required documents through the Commons.

Peer Review Conflict of Interest

Can reviewers review applications for which they have a conflict of interest?

No. Members of <u>peer review</u> committees must leave the room during discussions of grant applications in which they or close associates have an interest that could bias their evaluations. See <u>reviewer conflict of interest</u> information.

If reviewers are in conflict with one contract proposal, they should not participate in the review of any proposals in response to the specific RFP.